

## REMARKS/ARGUMENTS

### In the Drawing Figures:

In new Fig. 3, a liner is shown to be used as an element of the present invention.

### In the Claims:

Claims 44-63 and 79-83 remain pending in the present application. Claims 1-42 have been previously canceled. Claims 43, and 64-78 have been withdrawn. Claims 44, 45, 50, 57, 60, 79, 81 and 83 are currently amended.

### Non-Statutory Double Patenting Rejection of Claims 44-63 and 79-83

The Examiner rejected claims 44-63 and 79-83 under the judicially created doctrine of obvious-type double patenting as being unpatentable over the claims of U.S. Patent No. 5,702,489. As the present application and U.S. Patent No. 5,702,489 are of common ownership, the Applicant has enclosed with this Response, a terminal disclaimer in compliance with 37 C.F.R. § 1.321(c). Consequently, the Applicant respectfully submits that the Examiner's double patenting rejection of claims 44-63 and 79-83 may now be properly withdrawn.

### Objection to Claims 44-49, 60, and 81-83 Under 35 U.S.C. § 112

The Examiner objected to claims 44-49, 60, and 81-83 under 35 U.S.C. § 112, second paragraph as being indefinite for containing various informalities. The Applicant has amended claims 44-49, 60, and 81-83 to correct these informalities. As such, the Applicant respectfully submits that the Examiner's 35 U.S.C. § 112 rejection of claims 44-49, 60, and 81-83 may now be properly withdrawn.

Rejection of Claims 44, 45, 47, 48, 50-53, 55 and 83 Under 35 U.S.C. § 102(b)

The Examiner rejected claims 44, 45, 47, 48, 50-53, 55 and 83 under 35 U.S.C. § 102(b) as being anticipated by Surerus (DE 27 29 800 A1). As the Applicant does not believe Surerus to teach the subject matter of claims 44, 45, 47, 48, 50-53, 55 and 83, the rejection is respectfully traversed.

Surerus does not teach or suggest the use of a sleeve (liner) for placement over the residual limb of an amputee. The Applicant respectfully submits that what is represented by the dashed lines of Fig. 3 of Surerus is merely the outer surface of the amputee's residual limb. Further, the use of such a liner would not have been obvious at the time of invention of the subject matter of Surerus (filed 07/01/1977), as is asserted by the Examiner. The Applicant has submitted a Declaration under 37 C.F.R. § 1.132 along with this Response. As can be understood from said Declaration, the use of sleeves or liners with any type of prosthesis employing a suction suspension system did not occur until approximately the mid 1990's. Prior to this time, suction suspension systems relied on contact between the skin of the amputee's residual limb and the interior surface of the prosthetic socket to produce a secure fit of the residual limb. Therefore, the use of a liner with the apparatus of Surerus could not have been obvious at the time of invention thereof. As such, the socket of Surerus also would not be configured to receive a liner-covered residual limb.

Surerus also fails to teach a base attached to an interior distal end of a prosthetic socket, or a base having a channel therein that passes through a proximate surface of the base. The element residing under the pneumatic ring (22), which the Examiner

refers to as a base, is not the equivalent of the base recited in the rejected claims. At best, the element appears to be a thin disk that rests atop a ledge at some distance from the distal end of the limb. There appears to be a hole in the center of the disk, but there is no indication that the disk includes a channel. In fact, the Applicant asserts that the disk appears far too thin to have a channel. If the Examiner is asserting that the hole in the disk is equivalent to the channel recited in the present application, the Applicant respectfully disagrees. The hole in the disk of Surerus provides an indiscriminate passageway into a lower portion of the socket. It is not a channel, which by definition means a route, course, channel or furrow, etc., through which something (in the present application, air) passes. The channel of the present invention is shown to specifically direct air from the chamber above the base, through the body of the base, and to the outside atmosphere. The hole in the disk of Surerus does no such thing.

Additionally, the disk of Surerus is not attached to the interior distal end of the socket, as is the base of the present invention. Rather, the disk resides at some distance from the distal end of the socket. This location allows for a large cavity to exist between the disk and the distal end of the socket. Such a cavity increases the opportunity for air to be remain trapped within the socket. Mounting the base in the distal interior of the socket, as in the present invention, reduces the area wherein trapped air can reside. The location of the disk in Surerus also increases the overall length of the socket. As stated in the present application, an elongated socket is undesirable because it may be unusable by amputees with long residual limbs. This may be especially true with immediately above-knee amputations, as the socket may extend the thigh portion of the prosthesis beyond where the knee joint should be.

Surerus also fails to teach a duct extending through the socket and connected to a channel in a base. The duct (24), as identified by the Examiner appears to be coupled to a valve at one end. However, the other end of the duct appears to be coupled to a connector of an air bladder - not to a channel, or even a hole, in the disk. Thus, the duct cannot be used to transfer air from within the socket interior to the outside of the socket, as is accomplished in the present invention. Rather, the duct of Surerus is used only to inflate and deflate the air bladder that appears to be provided for assisting in the cushioning (along with inserts (23)) of the distal end of the residual limb.

Therefore, the Applicant submits that there are material differences between the teachings of Surerus and the subject matter of the rejected claims. As such, the Applicant respectfully submits that Surerus cannot support a rejection of claims 44, 45, 47, 48, 50-53, 55 and 83 under 35 U.S.C. § 102(b).

Rejection of Claims 44, 46, 47, 49, 50, 52-54, 56, 57, 59-63 and 79-83

Under 35 U.S.C. § 102(b)

The Examiner rejected claims 44, 46, 47, 49, 50, 52-54, 56, 57, 59-63 and 79-83 under 35 U.S.C. § 102(b) as being anticipated by Toles (US 980,457). As the Applicant does not believe Toles to teach the subject matter of claims 44, 46, 47, 49, 50, 52-54, 56, 57, 59-63 and 79-83, the rejection is respectfully traversed.

Toles does not teach or suggest the use of a sleeve (liner) for placement over the residual limb of an amputee. The sack or sheath of Toles is not a liner for wearing over the residual limb, but rather is physically attached to, and remains with, the prosthetic limb socket.

Toles also fails to teach the use of a base or base-plate in general, and definitely does not teach a base or base-plate that is attached to the distal interior of a prosthetic limb socket. Rather, the element (18) of Toles identified by the Examiner as a "base," is merely a hollow tube which functions as a rudimentary valve, and is affixed within the socket by a longitudinally displaceable bolt/nut assembly that holds the tube at *some distance* from the distal end of the socket. If element (18) were truly attached to an interior distal end of the socket, it would not be possible for the extensive assembly of elements (e.g., 15, 17, 20, 21, 22, 24) to reside therebelow.

The valve (15, 18, 19') of Toles is not provided to control the flow of air to and/or from the interior of the prosthetic socket. Rather, the valve is a simple one-way valve, that allows accumulated moisture to drain from within the sack. As the present invention employs a liner to cover the residual limb, there is no need to drain perspiration from within the socket, because any perspiration would be retained within the liner. Additionally, because the valve appears to be a one-way valve, it would not be possible to connect a pump for providing a forced transfer of air into the prosthetic socket. Toles also does not teach the use of a flow control means for controlling the flow of air to and/or from the socket.

Toles also wholly fails to teach a means for using a base-plate located in an interior distal end of a prosthetic socket to secure an upright assembly portion of a prosthetic limb to the socket. As can be clearly seen in Fig. 1 of the present application, the upright assembly generally consists of the remainder of the prosthetic limb (e.g., lower leg, arm, etc.), and is affixed to the outside of the prosthetic socket. The upright assembly may be affixed to the socket by, for example, passing a bolt through the

upright assembly and socket wall, and threading the bolt into like-threaded holes in the base-plate residing within the socket interior. Thus, the socket wall at the distal end of the socket would be trapped between the base-plate and the upright assembly.

The structure of Toles that the Examiner equates with the upright assembly of the present invention, is wholly unrelated thereto. In Toles, the "upright assembly" identified by the Examiner is comprised of a threaded bolt/nut assembly to which the stump receiving sack is attached, and by which the sack can be stretched. The structure is contained entirely within the interior of the prosthetic socket, with the bolt portion thereof affixed (secured) to the interior wall of the socket. None of the structure passes through the socket wall, or is attached to the tube (18) that the Examiner has equated with the base-plate of the present invention.

Further, in Toles, there is no duct connecting the channel (opening) in the tube to the outside of the socket. Any air passing through the valve merely exits into a lower portion of the socket, and then out through a permanent opening located therein for adjusting the position of the bolt/nut assembly. This design also causes a problem that is avoided by the design of the present invention: namely, the tube/sack tensioning apparatus requires a prosthetic socket of substantial length, as the structure required to accommodate the sack tensioning apparatus produces a large void in the bottom of the socket. As discussed above with respect to the Surerus reference, a long socket can make it difficult, if not impossible, for an amputee with a long residual limb to wear such a prosthesis.

Therefore, the Applicant submits that there are material differences between the teachings of Toles and the subject matter of the rejected claims. As such, the Applicant

respectfully submits that Toles cannot support a rejection of claims 44, 46, 47, 49, 50, 52-54, 56, 57, 59-63 and 79-83 under 35 U.S.C. § 102(b).

Rejection of Claims 44, 45, 47, 49-53, and 56-58 Under 35 U.S.C. § 103(a)

The Examiner rejected claims 44, 45, 47, 49-53, and 56-58 under 35 U.S.C. § 103(a) as being unpatentable over Sandmark (SE 8801686 A). As the Applicant does not believe Sandmark to teach or suggest the subject matter of claims 44, 45, 47, 49-53, and 56-58, the rejection is respectfully traversed:

Sandmark does not teach or suggest the use of a sleeve (liner) for placement over the residual limb of an amputee. The use of such a sleeve also would not have been obvious at the time of invention of the subject matter of Sandmark (filed 09/22/1987), as is asserted by the Examiner. The Applicant has submitted a Declaration under 37 C.F.R. § 1.132 along with this Response. As can be understood from said Declaration, the use of sleeves or liners with any type of prosthesis employing a suction suspension system did not occur until approximately the mid 1990's. More specifically, use of a liner with an above-knee prosthesis employing a suction suspension system, as is described in Sandmark, did not gain acceptance until approximately 2001. Prior to this time, suction suspension systems relied on contact between the skin of the amputee's residual limb and the interior surface of the prosthetic socket to produce a secure fit of the residual limb. The residual limb was pulled into the socket by use of a removable bandage, which typically passed through, and was removed via, an aperture in the side of the prosthetic socket. (See also, page 1,

second paragraph of Sandmark). Consequently, the use of a liner with the apparatus of Sandmark could not have been obvious at the time of invention thereof.

Likewise, the use of a valve with the device of Sandmark would not have been obvious because the invention does not contemplate *maintaining* the airspace (4) within the socket in an evacuated or pressurized state. (See page 5, lines 18-19). Rather, it is intended that the airspace remain ventilated. Thus, there would be no reason to use a valve. Additionally, coupling a valve to the duct (6) would not have been obvious, again, because there would be absolutely no need to use a valve. The duct in Sandmark is not connected to the base (or opening in the base), it is merely held in place by the amputee for the brief period for which it is needed. The duct does not remain in contact with the base while the amputee uses the prosthetic limb. Thus, the vacuum and/or pressure provided by the pump could be "shut off" as desired simply by moving the duct away from the opening in the base. As it is not intended that the socket be maintained in an evacuated or pressurized state, there is no concern that air would thereafter enter or leave the socket and, therefore, a valve would be unnecessary.

The Applicant also respectfully disagrees with the Examiner's assertion that Sandmark teaches that element (7) (receptacle) is capable of being removed from element (8) (wall of the socket). In the present invention, the base of the valve assembly is designed to be removable from within the distal interior of the prosthetic socket. For example, the base may be retained by bolts. Element (7) of Sandmark does not appear to be removable. Rather, element (7) appears to have both an upper and lower flange that traps a portion of the socket wall (8) therebetween. (See Fig. 4). Thus, it does not appear that element (7) was designed with removability in mind. The



Applicant respectfully submits that many elements of a given apparatus may often be removed, whether or not such was the intent of the inventor. However, if removal requires damage to, or at least unintended/undesirable deformation of, one or more elements of the apparatus (as would appear to be required here), the element can hardly be said to be "adapted to be removable" (i.e., removably fitted).

The Applicant further respectfully disagrees with the Examiner's assertion that a it would have been obvious to couple a check valve to the opening (7) in the socket (8) of Sandmark. Sandmark teaches that the pump (5) is to be used to assist an amputee in both the donning and doffing of a prosthetic limb, by evacuating and pressurizing the prosthetic socket, respectively. During donning of the prosthetic limb, the amputee connects one end of the duct (6) to the vacuum port of the pump and holds the other end of the duct to the opening (7) in the socket (8), thereby creating a vacuum within the socket by which the residual limb is drawn in. During doffing of the prosthetic limb, the amputee connects one end of the duct (6) to the exhaust port of the pump and holds the other end of the duct to the opening (7) in the socket (8), thereby pressurizing the interior of the socket and helping to expel the residual limb therefrom. Therefore, a check valve would render one of these desired modes inoperable, as a check valve would not allow the passage of air through the opening (7) in both directions. Consequently, not only would a check valve not have been obvious, the use of a check valve would render the invention at least partially inoperable.

Therefore, the Applicant submits that there are material differences between the teachings of Sandmark and the subject matter of the rejected claims. As such, the

Applicant respectfully submits that Sandmark cannot support a rejection of claims 44, 45, 47, 49-53, and 56-58 under 35 U.S.C. § 103(a).

Rejection of Claims 50, 56 and 57 Under 35 U.S.C. § 103(a)

The Examiner rejected claims 50, 56 and 57 under 35 U.S.C. § 103(a) as being unpatentable over Catranis (US 2,530,285). As the Applicant does not believe Catranis to teach or suggest the subject matter of claims 50, 56 and 57, the rejection is respectfully traversed.

Catranis does not teach or suggest the use of a sleeve (liner) for placement over the residual limb of an amputee. Further, the use of such a liner would not have been obvious at the time of invention of the subject matter of Catranis (filed 12/11/1947), as is asserted by the Examiner. The Applicant has submitted a Declaration under 37 C.F.R. § 1.132 along with this Response. As can be understood from said Declaration, the use of sleeves or liners with any type of prosthesis employing a suction suspension system did not occur until approximately the mid 1990's. More specifically, use of a liner with an above-knee prosthesis employing a suction suspension system, as is described in Catranis, did not gain acceptance until approximately 2001. Prior to this time, suction suspension systems relied on contact between the skin of the amputee's residual limb and the interior surface of the prosthetic socket to produce a secure fit of the residual limb. Therefore, the use of a liner with the apparatus of Catranis could not have been obvious at the time of invention thereof. As such, the socket of Catranis also would not be configured to receive a liner-covered residual limb, or to provide sealing contact with the outer surface of a liner.

Catranis also operates to maintain a partial pressure within a chamber of the prosthetic socket that resides below the residual limb. The pressure is required to actuate a pressure sensitive knee-lock mechanism. The check valve acts to expel air based on a set pressure point, but also can draw in air if the pressure becomes too low (i.e., if the downward force of the residual limb forces too much air out of the socket). In contrast, the valve assembly of the present invention seeks to expel as much air as possible from within the socket, as any trapped air may have a negative effect on the suction retention of the prosthetic limb, and may cause embarrassing noises if allowed to escape upward through the socket opening.

Therefore, the Applicant submits that there are material differences between the teachings of Catranis and the subject matter of the rejected claims. As such, the Applicant respectfully submits that Catranis cannot support a rejection of claims 50, 56 and 57 under 35 U.S.C. § 103(a).

Rejection of Claims 49, 56-60, 62 and 63 Under 35 U.S.C. § 103(a)

The Examiner rejected claims 49, 56-60, 62 and 63 under 35 U.S.C. § 103(a) as being unpatentable over Surerus. As the Applicant does not believe Surerus to teach or suggest the subject matter of claims 49, 56-60, 62 and 63, the rejection is respectfully traversed.

The non-obviousness of using a liner with the apparatus of Surerus has been discussed above. The valve of Surerus appears to be a two-component valve. It appears that air can be supplied to or released from the air bladder through a centrally-located valve (valve II). It also appears that the other portion of the valve assembly

(valve I) may be able to release air from within the chamber in the bottom of the prosthetic limb socket. However, valve I appears to be designed to prevent the expulsion of air from within the socket without the manual depression of the valve body (11). Depression of the valve body will cause a compression of the springs and cause the seals (6) to be moved out of sealing engagement with a mating flange of the threaded valve insert (4). In this position, it would appear that air from within the socket could flow past the wings (10) of the lower portion of the valve body (11) and out of the socket. However, because valve I is shown to be biased in a closed position, a pressure increase within the socket will only reinforce the desire of the valve to remain closed. To allow the expulsion of air from within the socket will always require manual activation of the valve. Consequently, the valve can never spontaneously open in response to an increase in socket pressure, as can the check valve of the present invention.

Additionally, the device of Surerus lacks a channel for directing air from the interior of the socket to the exterior of the socket. Therefore, the Applicant submits that there are material differences between the teachings of Surerus and the subject matter of the rejected claims. As such, the Applicant respectfully submits that Surerus cannot support a rejection of claims 49, 56-60, 62 and 63 under 35 U.S.C. § 103(a).

### **CONCLUSION**

The Applicant has amended claims 44, 45, 50, 57, 60, 79, 81 and 83 in this Response to more clearly describe the present invention. The Applicant has also

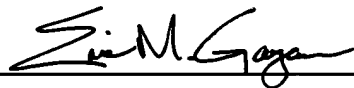
distinguished the subject matter of the present invention over the teachings of the references cited as prior art by the Examiner.

Therefore, the Applicant respectfully submits that the present application is now in condition for allowance, and entry of the present amendment and allowance of the application as amended is earnestly requested. Telephone inquiry to the undersigned in order to clarify or otherwise expedite prosecution of the present application is respectfully encouraged.

Respectfully submitted,

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By: \_\_\_\_\_



Eric M. Gayan  
Registration No. 46,103  
Standley & Gilcrest LLP  
495 Metro Place South  
Suite 210  
Dublin, Ohio 43017-5319  
Telephone: (614) 792-5555  
Facsimile: (614) 792-5536  
E-mail: egayan@standleyandgilcrest.com